

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG**
MDL No. 2738

THIS DOCUMENT RELATES TO ALL CASES

**THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF
LAW IN RESPONSE AND OPPOSITION TO J&J'S CONDITIONAL
MOTION TO EXCLUDE CERTAIN PLAINTIFFS' EXPERTS' OPINIONS
FOR LACK OF QUALIFICATIONS**

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The Plaintiffs' Steering Committee ("PSC") submits this Memorandum of Law in response and opposition to *Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Conditional Motion to Exclude Certain Plaintiffs' Experts' Opinions for Lack of Qualifications* [Dkt. No. 9736-3] (hereinafter "Defs. Mem., Qualifications"). For the foregoing reasons, this Court should deny Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s ("hereinafter "J&J") motion.

I. INTRODUCTION

J&J's "conditional[]" challenge to the PSC's experts cannot prevail under the Third Circuit's standard for admission of expert testimony. Contrary to J&J's largely unfounded arguments, the PSC's experts are well-qualified to offer all proffered testimony, providing expertise extensively supported by their knowledge, training and experience in their respective fields. J&J primarily challenges the PSC's experts' qualifications to offer opinions about biological plausibility, and the presence of carcinogenic contaminants, including asbestos, in Johnson's Baby Powder and *Shower-to-Shower* sold to consumers ("Talcum Powder Products"). The PSC addresses these recurring issues in general sections below, followed by a discussion of expert-specific qualifications.

II. THIRD CIRCUIT LEGAL STANDARD FOR ASSESSING EXPERT QUALIFICATIONS

The PSC incorporates the *Plaintiffs' Steering Committee's Omnibus Brief Regarding Daubert Legal Standard and Scientific Principles for Assessing General Causation*¹ and highlights the following important points:

J&J concede that the PSC's experts are as qualified as defense experts as to their proffered testimony² and therefore challenge their qualifications only "in anticipation" of "the PSC' qualification challenges" of "J&J' experts."³ J&J states, "In light of the experience of the experts on both sides and the complexities of the scientific issues in this litigation, the J&J defendants believe that it would be a waste of time and resources for the parties and the Court to spend a significant amount of energy debating whether the parties' experts are qualified to offer the opinions in their reports."⁴

J&J acknowledges that the Third Circuit follows liberal qualification requirements, recognizing that a "broad range of knowledge, skills, and training

¹ Dkt. No. 9732 (hereinafter "PSC's *Omnibus Memorandum*").

² Defs.' Mem., Qualifications, at 1 ("experts for both parties are trained and experienced in overlapping fields – such that any qualifications challenge to one party's experts would apply equally to witnesses on the other side as well.").

³ *Id.* at 1-2 ("[I]n anticipation of the PSC' qualification challenges with respect to J&J' experts, the J&J defendants respectfully submit this Memorandum to address the PSC' experts' qualifications.... J&J thus conditionally move to exclude the opinions of these experts").

⁴ *Id.* at 1.

qualify an expert,”⁵ and noting that “most arguments about an expert’s qualifications relate more to the weight to be given the expert’s testimony than to its admissibility.”⁶

J&J also presents their expert qualification motion as a “conditional” challenge of each expert witness. This contention of compromise “in anticipation of the PSC’ qualification challenges,” does not reflect the Third Circuit standard for expert qualification.

The Third Circuit, instead, looks to the Federal Rules of Evidence, which govern the admissibility of expert testimony.⁷ Fed. R. Evid. 702 provides that experts may be permitted to testify if they are “qualified” “by knowledge, skill, experience, training or education” and will “help the trier of fact to understand the evidence or to determine a fact in issue.”⁸ Fed. R. Evid. 702 additionally requires that (1) the testimony be “based upon sufficient facts or data;” (2) the testimony be “the product of reliable principles and methods;” and (3) the expert witness have “reliably applied the principles and methods to the facts of the case.” The Third

⁵ *Id.* at 2 (citing *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008)).

⁶ *Id.* at 2 (citing *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782–83 (3d Cir. 1996)).

⁷ See *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, No. CIV.A. 08-08, 2013 WL 1558690 (D.N.J. Apr. 10, 2013).

⁸ *Id.* (citing Fed. R. Evid. 702).

Circuit has come to interpret these elements as a “trilogy” of restrictions: qualification, reliability, and fit.⁹

Qualification, specifically, refers to the requirement that a witness have “specialized expertise.”¹⁰ The Third Circuit interprets this language liberally.¹¹ While acknowledging that the expert witness “must possess skill or knowledge greater than the average layman,” it recognizes “no litmus test to qualify an expert.”¹² The Court qualifies experts with a “broad range of skills and training,”¹³ and “eschew[s] imposing overly rigorous qualification requirements,” noting that “most arguments about an expert’s qualifications relate more to the weight to be given the expert’s testimony than to admissibility.”¹⁴

⁹ *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *McKenzie v. Dematic Corp.*, No. CV 3:12-250, 2016 WL 707485 (W.D. Pa. Feb. 22, 2016).

¹⁰ *Id.*; see also *Pineda*, 520 F.3d at 244; *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998).

¹¹ *Ford v. Ford Motor Co.*, 311 F. Supp. 3d 667, 673–74 (D.N.J. 2017) (citing *Schneider ex rel. Estate of Schneider*, 320 F.3d at 405).

¹² *Elcock*, 233 F.3d at 741 (citing *Waldorf*, 142 F.3d at 625) (accord *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1056 (3d Cir. 1997)).

¹³ *Ford*, 311 F. Supp. 3d at 674.; see also *Pineda*, 520 F.3d at 244; *Burton v. Danek Med., Inc.*, No. CIV.A. 95-5565, 1999 WL 118020 (E.D. Pa. Mar. 1, 1999); *In re Paoli R.R. Yard PCB Litig.* (“Paoli II”), 35 F.3d 171, 741 (3rd Cir. 1994); *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 855 (3d Cir. 1990).

¹⁴ *Holbrook*, 680 F.3d at 782.

To this end, the Third Circuit has reasoned that it is an “abuse of discretion” to exclude expert testimony solely because a proffered expert is not the “best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.”¹⁵ For instance, the Court has noted that its jurisprudence is inconsistent with insistence that a qualified expert meet specific degree or background requirements.¹⁶

III. J&J’S CHALLENGES ARE “CONDITIONAL”

Despite J&J’s almost forty pages of argument to exclude the opinions of the PSC’s experts based on their qualifications, J&J states that the entire exercise is a “waste of time and resources.”¹⁷ J&J effectively concede that the PSC’s experts are qualified in their respective fields: their arguments are “conditional[],” as they only “move to exclude the opinions of these experts in part or in full based on lack of qualifications to the extent the Court considers the PSC’s motions related to qualifications.”¹⁸

J&J repeatedly asks the Court to exclude experts only where the PSC argued for exclusion on similar grounds. For example, the PSC asks the Court to exclude

¹⁵ *Id.*

¹⁶ *Id.* (quoting *Paoli I*, 916 F.2d at 856) (“Insistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area.”).

¹⁷ Defs.’ Mem., Qualifications at 1.

¹⁸ *Id.*

Dr. Anne McTiernan, among other experts, on the grounds that she “has not published any articles on the causes of ovarian cancer” and that her opinions were formed after she was retained in the litigation.¹⁹ This is just an example of J&J’s anemic arguments. Dr. McTiernan is in fact imminently qualified, has published several manuscripts on gynecologic cancer, specifically ovarian cancer, and incredibly was an investigator in one of the only three cohort studies significant to this litigation. The challenge to Dr. McTiernan’s qualifications, is an example of J&J’s over-reach.²⁰

Where J&J argues to exclude an expert *if* the PSC argued for exclusion on similar grounds, J&J fails to explain why those grounds are relevant to a specific expert’s qualifications. J&J’s contentions do not reflect the Third Circuit standard for expert qualification. J&J’s challenges to experts only on the presumption that “the PSC did it too” cannot prevail.

As the Court is aware, all experts are not automatically qualified. Though the Third Circuit standard is liberal as to qualifications, it is not non-existent. The PSC raised significant issues regarding the qualifications of Defendants’ experts for the

¹⁹ *Id.* at 17-18.

²⁰ Houghton SC, Reeves KW, Hankison SE, Crawford L, Lane D, Wactawski-Wende J, et al. Perineal powder use and risk of ovarian cancer. *Journal of the National Cancer Institute*. 2014;106(9) (Women’s Health Initiative cohort study (WHI)), see attached as **Exhibit 1**.

opinions being offered. The parties' respective motions should be considered taking into account the applicable law and the education, training and expertise of the respective expert for the opinions being offered.

IV. J&J'S CHALLENGE THAT SEVERAL OF THE PSC'S EXPERT ARE NOT QUALIFIED TO OFFER OPINIONS ABOUT BIOLOGICAL PLAUSIBILITY IS MERITLESS

J&J' "conditionally" challenges seven (7) expert witnesses²¹ specifically as to their qualifications to offer opinions about "biological plausibility."

Biological plausibility is one part of a Bradford Hill causation analysis.²² In 1965, Bradford Hill distinguished biological plausibility from causation: "[I]t will be helpful if the causation we *suspect* is biologically *plausible*."²³ The plain meaning of the term biological plausibility, should not be overlooked: assessing biological plausibility entails assessing whether it makes biological sense in light of what is known that the exposure to the agent (talcum powder) causes the outcome (ovarian

²¹ The seven witnesses are: Michael Crowley, Ph.D.; Shawn Levy, Ph.D.; Patricia Moorman, Ph.D., M.S.P.H.; Laura Plunkett, Ph.D., D.A.B.T.; Sonal Singh, M.D., Ph.D.; Rebecca Smith-Bindman, M.D.; and Judith Zelikoff, Ph.D.

²² See *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 2013 WL 1558690, at *3; accord *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 466, 474 (E.D. Pa. 2014).

²³ A.B. Hill, The environment and disease: association or causation? *Proc. Royal Soc. Med. B*, 58, 295-300 (1965) ("Hill (1965)") (emphasis added), see attached as **Exhibit 2**.

cancer). Put differently, is there a biological reason that is inconsistent with causation? The seven (7) PSC experts are experts in the fields of medicine, epidemiology, pharmacology, biochemistry, microbiology, chemistry, pathology, and toxicology, and all have the requisite training to assess biological plausibility. All certainly “possess skill or knowledge greater than the average layman” on the issues pertaining to biological plausibility. The seven (7) experts have various health science backgrounds, such that assessing biological certainly fits within their areas of expertise.

The *Reference Manual on Scientific Evidence* describes biological plausibility as a judgment based on existing knowledge as to whether an agent plausibly could cause an adverse outcome.²⁴ Biological plausibility exists where there is “evidence supporting the causal chain” and “depends on the biological knowledge of the day.”²⁵ “Plausibility” is not the same as “probability.”²⁶²⁷

²⁴ Green, *et al.*, *Reference Manual on Scientific Evidence*, Reference Guide on Epidemiology, at 604-05 (3d Ed. 2011).

²⁵ Howick, *et al.*, The evolution of evidence hierarchies: what can Bradford Hill’s ‘guidelines for causation’ contribute? *J. Royal Soc. Med.*, 102:186-194, at 187-189 (2009) (“Howick (2009)”), see attached as **Exhibit 3**.

²⁶ *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011).

²⁷ For additional detail on biological plausibility see the PSC’s *Memorandum of Law in Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer, Inc.’s Motion to Exclude the PSC’s Experts’ Opinions Related to Biological Plausibility* and the PSC’s *Omnibus Memorandum of Law in Response and Opposition to Defendants Johnson & Johnson and Johnson & Johnson Consumer*

It similarly follows that assessing evidence of biological plausibility is not synonymous with requiring proof of the causal mechanism.²⁸ “The fact that the mechanism remains unclear does not call the reliability of the opinion into question.”²⁹ Therefore, experts qualified to opine on biological plausibility need not have posited a known biological mechanism, nor do they need to have the same qualifications as would be needed to make that assessment.

Each of the PSC’ experts who offer biological plausibility opinions are qualified to do so. Assessing plausibility is within the wheelhouse of experts in medicine, epidemiology, pharmacology, biochemistry, microbiology, chemistry, pathology, toxicology, and pharmacy. The PSC’s experts are qualified to opine that it “makes sense” that Talcum Powder Products “causes the outcome,” ovarian cancer, based on “the biological knowledge of the day” based on the perspective of their own disciplines and fields of expertise.³⁰

Inc.’s Motion to Exclude Plaintiffs’ General Causation Opinions both being filed simultaneously herewith.

²⁸ See *Bartoli v. Novartis Pharm. Corp.*, No. CIV.A. 3:13-0724, 2014 WL 1515870 (M.D. Pa. Apr. 17, 2014); see also *Perry v. Novartis Pharm. Corp.*, 564 F. Supp. 2d 452, 463 (E.D. Pa. 2008) (requiring only “good grounds” that a biological mechanism existed).

²⁹ *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003).

³⁰ See Hill (1965); accord Howick (2009).

V. J&J'S CHALLENGE THAT SEVERAL OF THE PSC'S EXPERTS ARE NOT QUALIFIED TO OFFER OPINIONS ABOUT ASBESTOS AND OTHER CARCINOGENS CONTAINED IN TALCUM POWDER PRODUCTS IS MERITLESS

J&J also conditionally challenges the qualifications of several of the PSC's experts who offer opinions regarding asbestos and other carcinogenic substances that have been found in J&J's Talcum Powder Products.³¹ J&J claims that, because the PSC' experts have not tested or examined talcum powder tangibly or through a microscope, and because they lack the expertise to do that, they cannot testify to their knowledge of asbestos evidence.

It is important to be clear about the specific opinions being challenged.³² These experts do nothing more than state that they have seen evidence that asbestos and other substances continue to be found in talcum powder. Other expert witnesses are being offered to testify about their testing and their findings, as well as their opinions about the presence of asbestos and other carcinogens in the Talcum Power Products. But the experts challenged here offer no such opinions. Their observations,

³¹ J&J has made this challenge to Sarah Kane, M.D.; Shawn Levy, Ph.D.; Anne McTiernan, M.D., Ph.D.; Patricia Moorman, Ph.D., M.S.P.H.; Laura Plunkett, Ph.D., D.A.B.T.; Jack Siemiatycki, Ph.D.; Rebecca Smith-Bindman, M.D.; and Judith Zelikoff, Ph.D.

³² For additional detail, see the *PSC's Memorandum of Law in Opposition to Johnson & Johnson and Johnson & Johnson Consumer, Inc.'s Memorandum of Law in Support of Motion to Exclude the PSC's Experts' Asbestos-Related Opinions* which is being filed simultaneously herewith and is incorporated herein.

that they have seen evidence that there is asbestos (and other substances – fibrous talc, fragrances, and heavy metals) in the Talcum Powder Products do not require that they have themselves examined asbestos (and other substances - fibrous talc, fragrances, and heavy metals) as a toxicologist, geologist, or mineralogist might, or that they have the expertise themselves to determine the contents of the Talcum Powder Products. Instead, the challenged experts report that they have observed this evidence only as a predicate or foundation for their further opinions regarding the implications of those substances being in the talcum powder; *i.e.*, how does the presence of these substances affect their assessment of biological plausibility, and whether it strengthens their general causation opinion.

J&J further confuses the opinions of several experts by suggesting that their biological plausibility or causation opinions *depend* on the presence of asbestos (and other substances - fibrous talc, fragrances, and heavy metals) in Talcum Powder Products. However, none of these experts opine that cosmetic talc is capable of causing ovarian cancer *only because* it contains with these constituents. These experts consistently opine that the evidence of the talcum powder's composition is an element of their review, which adds to their assessment of biological plausibility and strengthens their causation opinions between Talcum Powder Products and ovarian cancer.

VI. EACH OF THE PSC'S EXPERTS IS QUALIFIED TO TESTIFY AS TO THEIR EXPERT OPINIONS

A. Arch Carson, MD, Ph.D.

Dr. Carson is a physician who has specialized in the practice of medical toxicology since 1991. He is currently an Associate Professor at the University of Texas School of Public Health, Department of Epidemiology. He has medical and toxicology degrees and is board certified in Occupational Medicine.³³

Dr. Carson's professional activities have included patient care, basic and applied research, instruction of medical students and post-graduate medical trainees, and professional consulting. He has been a program director of the NIOSH-funded Education and Research Center at the University of Texas for 19 of the last 21 years. Dr. Carson has previously been accepted as an expert in the health effects of environmental exposures.³⁴

Dr. Carson is well-qualified to perform a Bradford Hill analysis of the causal relationship between talcum powder and ovarian cancer. In this regard, J&J's' first contention that Dr. Carson is unqualified to rely on, or offer opinions grounded in, epidemiology because he is not formally trained in epidemiology is inconsistent with

³³ Deposition of Arch Carson, MD, Ph.D., Jan. 19, 2019 ("Carson Dep.") at 239:6-8, attached as **Exhibit 4**; *see also* Expert Report of Arch Carson, MD, Ph.D., Nov. 16, 2018 ("Carson Rep."), Exhibit A (Carson CV), attached as **Exhibit 5**.

³⁴ Carson Dep. at 57:2-14.

Third Circuit jurisprudence.³⁵ Dr. Carson testified that he can be considered an epidemiologist based on his work.³⁶ “I deal a lot with epidemiologic work. I’m a faculty member in the Department of Epidemiology …and some may consider me an epidemiologist.” He certainly “possess[es] skill or knowledge greater than the average layman.”

J&J argues that Dr. Carson has no relevant background in gynecology, oncology, and cell biology, but that is incorrect. As to a woman’s reproductive tract, specifically, Dr. Carson testified, “I’ve taken it apart and put it back together again.”³⁷ He performs pelvic exams.³⁸ He also has performed OB/Gyn rotations, has participated in pelvic surgeries, and has a full understanding of human anatomy.³⁹

Dr. Carson explained that, he sees patients for workplace-related chemical and other exposures.⁴⁰ “[D]iagnostic investigation” is a routine part of his practice.⁴¹ Specifically regarding oncology, Dr. Carson testified that he frequently has “dealt …with issues of oxidative stress and health effects resulting from it.”⁴² Dr. Carson

³⁵ *Holbrook*, 680 F.3d at 782 (citing *Paoli I*, 916 F.2d at 856).

³⁶ Carson Dep. at 238:23-239:9.

³⁷ *Id.* at 207:16-207:22.

³⁸ *Id.* at 327:6-16.

³⁹ *Id.*

⁴⁰ *Id.* at 327:8-327:16; 328:5-329:2.

⁴¹ *Id.* at 328:17-329:2.

⁴² *Id.* at 137:14-138:2.

has “professional understanding and training” in oxidative stress,⁴³ a known cause of DNA mutagenesis and carcinogenesis, which is at issue with talcum powder.

J&J’s next contention that Dr. Carson admitted that he has no expertise in asbestos misstates Dr. Carson’s response.⁴⁴ Dr. Carson testified that he has “a significant amount of awareness and training regarding asbestos.”⁴⁵ In particular, Dr. Carson has had experience with asbestos in the context of occupational and general environmental exposures.⁴⁶ Combined with his medical background and skills and experience in diagnostic investigation, Dr. Carson is qualified to draw a causal inference between asbestos and disease risk.

Lastly, J&J’s contention that Dr. Carson’s opinions regarding heavy metals rely exclusively on the opinions of other experts is false. Dr. Carson’s analysis relied, instead, on his review of the totality of the evidence, including the cohort and case-control studies, which have shown statistically significant associations between Talcum Powder Products and ovarian cancers.⁴⁷ Dr. Carson’s review is integrated with his unique expertise in toxicology, informing that metals, such as chromium,

⁴³ *Id.*

⁴⁴ See *id.* at 55:11-55:20.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Carson Rep. at 7.

cobalt, and nickel, as well as fragrances, cause inflammation and add to the carcinogenicity of talcum powder.⁴⁸

Dr. Carson has the expertise in toxicology to assist the jury to understand the potential of carcinogenic heavy metals to be liberated in bodily fluids and tissues.⁴⁹ Further, this expertise informs his opinion that carcinogenic fragrance chemicals contribute to carcinogenicity in the ovary “because the ovaries have no intrinsic elimination system,” these toxins stall and sequester in ovarian tissue.⁵⁰

B. Robert Cook, Ph.D.

J&J conditionally challenge Dr. Robert Cook’s qualifications by arguing that Dr. Cook, a mining engineer and geologist, proffers opinions on mining and ore beyond his expertise.⁵¹ Specifically, J&J incorrectly identifies the following opinions as being outside Dr. Cook’s expertise:

- “Talc deposits derived by the alteration of serpentinites contain chrysotile and amphibole species in fibrous asbestiform habits, all of which are known carcinogens;”⁵²
- “Fibrous talc occurs in serpentinite-derived talc deposits, possibly by pseudomorphism of early chrysotile or

⁴⁸ *Id.*

⁴⁹ *Id.* at 9.

⁵⁰ *Id.*

⁵¹ Defs.’ Mem., Qualifications, at 5.

⁵² *Id.* at 5-6.

amphiboles. Such fibrous talc is not detectable by standard amphibole asbestos XRD screening...;”⁵³

- “Mine development and selective mining are not completely effective in avoiding ore and ore-related rock potentially containing amphiboles, chrysotile, and elevated amounts of heavy metals and arsenic;”⁵⁴
- “Analytical data indicate that nickel, chromium, and cobalt, known carcinogens, reach finished talc products in amounts above Johnson & Johnson’s (J&J) specified limits.”⁵⁵

Dr. Cook is amply qualified to testify on these matters. After earning his undergraduate degree in Mining Engineering, Dr. Cook obtained both his M.S. and Ph.D. in Geology.⁵⁶ Dr. Cook was a Professor at Auburn University, where he served more than 22 years as head of the Geology Department.⁵⁷ Presently, Dr. Cook is Professor Emeritus at Auburn University, Department of Geosciences.⁵⁸ He currently serves as President of Alabama Resource Management, Inc.⁵⁹

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Expert Report of Robert B. Cook, Ph.D, Nov. 16, 2018 (“Cook Rep.”) at 2, attached as **Exhibit 6**; *Id.* at Exhibit A (Cook CV) at 1.

⁵⁷ *Id.*

⁵⁸ Cook CV at 1.

⁵⁹ Cook Rep. at 2; Cook CV at 1.

Dr. Cook has held consultant positions for the United Nations, NASA, U.S. Department of Justice, and U.S. Department of Defense.⁶⁰ He has advised extensively regarding mining exploration, quarry development, and quality control, including sampling.⁶¹ Dr. Cook has consulted with mining companies regarding mineralogy and mining exploration for talc deposits.⁶² He has examined amphiboles and talc by XRD or x-ray diffraction.⁶³

Dr. Cook has authored approximately 100 research publications⁶⁴ and produced about 100 abstracts presented to learned societies.⁶⁵ Among his publications, Dr. Cook authored state mineralogy reviews for the States of Georgia and Alabama, respectively, including discussion of mineral deposits containing talc, asbestos, and heavy metals.⁶⁶

Dr. Cook testified that he has experience in scoping studies by which he provides “a compilation of all information available on a particular topic....”⁶⁷ In

⁶⁰ Cook Rep. at 2.

⁶¹ *Id.*; Cook CV at 24.

⁶² Deposition of Robert Cook, Ph.D., Jan. 31, 2019 (“Cook Dep.”) at 76:6-76:12 (emphasis added), attached as **Exhibit 7**.

⁶³ Cook Dep. at 81:8-82:4.

⁶⁴ *Id.*; Cook CV at 2–14.

⁶⁵ *Id.*

⁶⁶ Cook Rep. at 2.

⁶⁷ Cook Dep. at 462:4-462:16.

these instances, Dr. Cook was hired to inform companies whether it is worth their time to mine for particular ore in particular areas.⁶⁸ Similarly, here, Dr. Cook reviewed all information available regarding talc deposits and derivatives, and their respective locations.⁶⁹ Comparing scoping to his review here, Dr. Cook testified, “[I]t’s exactly what...I did here....it’s the same general intellectual exercise.”⁷⁰

Based on Dr. Cook’s experienced review, he was able to establish that “[t]alc from Vermont deposits used by J&J for its talcum powder products have elevated nickel (Ni), and cobalt (Co) as trace constituents” and that nickel, chromium, and cobalt are included in finished talc products.⁷¹

As to selective mining, particularly, Dr. Cook is qualified as evidenced by his above background and testimony specific to selective mining.⁷² Dr. Cook reviewed company documents, including core logs and mine photos regarding relevant talc mined in this matter.⁷³ Based on his knowledge, experience, and skill, Dr. Cook is

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Cook Rep. at 3.

⁷² Cook Dep. at 486:9-487:14.

⁷³ *Id.* at 487:19-488:7.

able to explain to a jury how the documents and photographs are evidence that J&J did not engage in selective mining, as proffered.

C. Michael Crowley, Ph.D.

J&J contests Dr. Michael Crowley's qualifications as to two issues: "(1) whether the fragrance chemicals in J&J's Talcum Powder Products are compliant with governmental and industry standards; and (2) whether such alleged chemicals can 'contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.'"⁷⁴ J&J's contention that Dr. Crowley is unqualified to testify on these issues is misguided.

Dr. Crowley has a B.S. degree in chemistry, M.S. in organic chemistry, and a Ph.D. in molecular pharmaceutics.⁷⁵ Presently, Dr. Crowley is president of a pharmaceutical development consulting firm, and he has served as consultant to more than 50 companies, primarily in the pharmaceutical industry, in the areas of proof of concept, formulation and product development, drug delivery, and clinical development, including a generation of FDA regulatory submissions.⁷⁶

⁷⁴ Defs.' Mem., Qualifications, at 8.

⁷⁵ Expert Report of Michael Crowley, Ph.D, Nov. 12, 2018 ("Crowley Rep.") at 14, attached as **Exhibit 8**; Deposition of Michael M. Crowley, Ph.D., Jan. 14, 2019 ("Crowley Dep.") at 341:20-23, attached as **Exhibit 9**.

⁷⁶ Crowley Rep. at 14.

Previously, he worked for a pharmaceutical company that developed novel drug products to treat infectious disease, as well as a contract research organization that provided formulation and drug product development services.⁷⁷ He is being offered as an expert in chemistry and chemical formulation and has ample experience studying, reviewing, and assessing the safety of all types of chemicals, including several that are in the J&J talcum powder products family.

Dr. Crowley has developed many pharmaceutical formulations, nutritional supplements, and food products, including over 50 formulations that have been tested in human clinical studies.⁷⁸ Dr. Crowley has created chemical formulas for various products including pharmaceuticals and cosmetic products. Examples include: a fragrance for use in a prenatal vitamin;⁷⁹ a cosmetic facial mask;⁸⁰ and pharmaceutical products for vaginal use.⁸¹

Dr. Crowley has authored or co-authored over 15 clinical study protocols, over 30 published articles and abstracts, and four book chapters relating to his

⁷⁷ *Id.*

⁷⁸ Crowley Rep. at 14; Crowley Dep. at 342:1-11.

⁷⁹ *Id.* at 52:14-23.

⁸⁰ *Id.* at 52:3-5.

⁸¹ *Id.* at 205:1-9.

work.⁸² He is an inventor with five United States patents and a number of foreign patents.⁸³ He has served as a reviewer for many peer-reviewed journals.⁸⁴

J&J first argues incorrectly that Dr. Crowley is unqualified to testify regarding J&J's' non-compliance because "he is not an expert on FDA regulations."⁸⁵ However, Dr. Crowley is not being offered as an "FDA regulations" expert. Dr. Crowley is being offered for his experience and knowledge in the review of safety profiles of chemicals for use in consumer products, including cosmetic products.⁸⁶ As this pertains to FDA regulations, Dr. Crowley regularly uses and reviews regulations to assess the safety of chemicals and is more than competent at understanding and applying FDA regulations.⁸⁷

J&J also mischaracterizes Dr. Crowley's methodology concerning J&J's non-compliance, noting that Dr. Crowley's "stated 'methodology' for reaching his ultimate conclusion was taking a list of fragrance chemicals...and then 'plugging'

⁸² Crowley Rep. at 14-15.

⁸³ *Id.* at 15.

⁸⁴ *Id.*

⁸⁵ Defs.' Mem., Qualifications at 8.

⁸⁶ Crowley Rep. at 14-15; Crowley Dep. at 341:20-342:11.

⁸⁷ *Id.* at 58:1-58:2 ("I write submissions to the FDA."); *Id.* at 59:10-59:11 ("I'm more than competent in understanding regulations."); *Id.* at 59:17-60:23 (Dr. Crowley has presented to the FDA on new drug applications as part of his consulting work for clients.); *Id.* at 122:21-123:3 (Dr. Crowley is familiar with and uses the FDA risk assessment models as part of his work.).

the ‘names of the chemicals’ into ‘Google or PubChem to see what [he] could find.’ This is a methodology issue, not a qualifications issue, and is also inaccurate. Dr. Crowley performed an exhaustive review of each fragrance chemical used in the J&J’s’ products with reference to numerous regulatory bodies, *in vivo* and *in vitro* studies, and journals/academic literature.⁸⁸

J&J *next* contests Dr. Crowley’s qualifications regarding the fragrance chemicals in talcum powder that can “contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.”⁸⁹ J&J specifically argues that Dr. Crowley has “never written or published papers on the topics of fragrance chemicals or talcum powder or addressing the question of talcum powder and purported inflammation or irritation.”⁹⁰ However, Dr. Crowley’s relevant experience, as set forth in detail above, is related to assessing the safety for use in cosmetic products, which is what he did in this case.

More generally, J&J mistakenly asserts that Dr. Crowley does not have “any prior experience in perennially-applied cosmetic products or with fragrance chemicals, asbestos, ovarian cancer, inflammation or irritation as it relates to talcum

⁸⁸ Crowley Rep. at 64.

⁸⁹ Defs.’ Mem., Qualifications at 8–9.

⁹⁰ *Id.* at 9.

powder.”⁹¹ Dr. Crowley specifically testified that, when working for Warner-Jenkinson, they “made fragrances” and that he has “used fragrances in pharmaceutical products.”⁹² “I have experience working with fragrances...”⁹³ Dr. Crowley also testified that he formulated products with talcum powder.⁹⁴ Further, Dr. Crowley testified to his experience in developing multiple vaginal products.⁹⁵

D. Sarah E. Kane, MD

J&J argues that Dr. Kane’s opinions in epidemiology and asbestos are “outside of her field.”⁹⁶ J&J defines her field (gynecologic pathology) too narrowly.

Dr. Kane is a certified gynecologic pathologist.⁹⁷ Dr. Kane’s training in pathology included the causes and mechanisms of disease, including gynecologic cancer.⁹⁸ After completing her training, Dr. Kane worked as a staff pathologist and Instructor of Pathology at Beth Israel Deaconess Medical Center (BIDMC),⁹⁹

⁹¹ *Id.* at 10.

⁹² Crowley Dep. at 52:14-52:23.

⁹³ *Id.*

⁹⁴ *Id.* at 65:16-65:22; 66:22-66:24; 70:22-71:17.

⁹⁵ *Id.* at 205:1-205:9.

⁹⁶ Defs.’ Mem., Qualifications at 11.

⁹⁷ Expert Report of Sarah Kane, MD, Nov. 15, 2018 (“Kane Rep.”) at 2, attached as **Exhibit 10**. Dr. Kane is certified by the American Board of Pathology in Anatomic Pathology, Clinical Pathology, and Cytopathology.

⁹⁸ *Id.*

⁹⁹ *Id.*

specializing in gynecologic pathology, perinatal pathology, and cytology.¹⁰⁰ Additionally, she served as BIDMC's Associate Director of the Cytopathology Fellowship Program, while also serving on numerous pathology department committees and teaching several medical courses at Harvard Medical School.¹⁰¹

Dr. Kane currently is a partner with Commonwealth Pathology Partners PC, a private practice group, and maintains staff privileges at several Massachusetts hospitals.¹⁰² Dr. Kane continues to follow the gynecologic pathology literature as a routine part of her practice.¹⁰³

Dr. Kane testified that causes of ovarian cancer "certainly" "fall[] into [her] area of expertise" as a gynecological pathologist¹⁰⁴ and that she is able to address ovarian cancer in terms of anatomic pathology and ovarian cancer pathogenesis.¹⁰⁵ Dr. Kane specifically is able to address the relationship between talcum powder and ovarian cancer in terms of plausibility and mechanism—both of which fall within the scope of anatomic/gynecologic pathology.¹⁰⁶

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Deposition of Sarah Kane, MD, Jan. 25, 2019 ("Kane Dep.") at 204:22-204:25, attached as **Exhibit 11**.

¹⁰⁵ *Id.* at 205:1-205:6.

¹⁰⁶ *Id.* at 205:1-205:15.

J&J's argument that Dr. Kane is unqualified to offer opinions based on her review of the epidemiology studies should be rejected because it is premised on a misunderstanding of the central role of epidemiology in the practice of pathology. Dr. Kane is knowledgeable as an anatomical and clinical pathologist about epidemiology.¹⁰⁷ An anatomical pathologist is "trained to look at epi[demiological] data[,]"—including study design, strengths, and weaknesses.¹⁰⁸ Dr. Kane routinely relies on review and interpretation of epidemiological studies as part of her regular clinical practice. She stated in her report that "pathologists must make clinical assessments based in part on medical and epidemiologic knowledge about and identification of causes, risk factors, clinical sequelae, morphologic and genetic features of disease."¹⁰⁹ She also stated that "[i]n order to produce accurate diagnoses, pathologists must be knowledgeable about the medical, scientific and epidemiologic evidence base."¹¹⁰ She stated that "[c]oming to a diagnosis requires knowledge of the medical, scientific and epidemiologic literature."¹¹¹

J&J's own pathology expert (Dr. Robert Kurman) knows that pathologists routinely deal with epidemiology and has published this point: "Most pathologists

¹⁰⁷ *Id.* at 205:7-205:15.

¹⁰⁸ *Id.* at 213:15-214:16.

¹⁰⁹ Kane Rep. at 2.

¹¹⁰ *Id.* at 3.

¹¹¹ *Id.*

are part-time epidemiologists as well. The two medical disciplines are more closely allied than many people realize.”¹¹² And, Dr. Kurman testified in his deposition that you cannot explain cancer pathology and etiology without some understanding and explanation of cancer biology and epidemiology. (“Cancer biology and epidemiology all come into play.”).¹¹³ Indeed, many chapters of Blaustein’s gynecologic pathology textbook and relied upon by medical students and physicians, refer to and explain the epidemiology behind pathology principles.¹¹⁴

Prior to this litigation, Dr. Kane’s practice included extensive literature reviews, including review regarding talcum powder and ovarian cancer.¹¹⁵ More particular to this litigation, Dr. Kane reviewed the epidemiologic literature in-depth regarding talcum powder and ovarian cancer from the perspective of a gynecologic pathologist and testified that epidemiology review is something pathologists do “on a regular basis.”¹¹⁶ Dr. Kane is well-versed in the epidemiological literature concerning the association between ovarian cancer and talcum powder use, as well

¹¹² Deposition of Robert Kurman, MD, Apr. 2, 2019 (“Kurman Dep.”) at 217:22-218:14, citing a chapter Kurman actually edited in *Blaustein’s Pathology of the Female Genital Tract*, 5th ed. (2002), Chapt. 27 entitled “Epidemiology,” attached as **Exhibit 12**.

¹¹³ *Id.* at 219:13-18.

¹¹⁴ *Id.* at 125:16-129:24, and 216:1-8.

¹¹⁵ Kane Dep. at 217:1-217:12.

¹¹⁶ *Id.* at 213:15-214:6.

as the non-epidemiologic pathology and biological evidence, citing in her report 186 sources from the literature.¹¹⁷

Dr. Kane of course relied on epidemiology studies concerning talcum powder and ovarian cancer, as part of her causal assessment, reasoning that this body of epidemiologic literature is extremely compelling, showing that the overwhelming majority of observational studies (34) over different periods of time in different populations that have found a positive association.¹¹⁸

J&J also challenges Dr. Kane's testimony regarding asbestos as "outside her expertise."¹¹⁹ As noted in the Introduction, Dr. Kane's opinions about asbestos do not require that she be an asbestos expert. Dr. Kane only proffers that she has seen evidence that talcum powder contains or has contained asbestos, and that there are biological plausibility implications *if* talcum powder includes asbestos. Dr. Kane is experienced in foreign-body responses, including those involving asbestos.¹²⁰ She is well-informed by the literature, and she has observed foreign body reaction, including granulomatous inflammation, "commonly" in her practice.¹²¹ As part of

¹¹⁷ *Id.* at 165:13-165:23.

¹¹⁸ *Id.* at 190:15-191:4; 191:10-191:15. ("...a lot the studies looking at talcum powder products and ovarian cancer are epidemiological studies, but they're extremely informative in that they are very consistent in their findings.").

¹¹⁹ Defs.' Mem., Qualifications at 12.

¹²⁰ Kane Dep. at 63:3-63:15.

¹²¹ *Id.* at 59:5-59:9.

her work in this case, her report details that she reviewed multiple scientific publications and studies that addressed issues pertinent to assessing the ovarian cancer risk posed by asbestos exposure, including human epidemiologic studies.

J&J also mischaracterizes her testimony as an admission that she is not an expert on asbestos issues in any respect.¹²² J&J improperly conflates Dr. Kane's testimony, that she is not an expert as to the mineral content of talcum powder, as an admission that she has no expertise—including no knowledge of the mutagenic, carcinogenic, and other foreign-body reactions—concerning asbestos.¹²³

Dr. Kane is clear that her “general causation opinion is not dependent on asbestos being in the product.”¹²⁴ “[Her] general causation opinion is based on whatever is in the bottle.”¹²⁵ That is primarily because the epidemiological studies assessed the risk of ovarian cancer to exposure to the talcum powder the same way: without specific focus on what were the “ingredients.”

¹²² Defs.’ Mem., Qualifications at 12.

¹²³ Kane Dep. at 321:21-322:3.

¹²⁴ *Id.* at 227–28.

¹²⁵ *Id.*

E. Mark Krekeler, Ph.D.

J&J “conditionally” contends that Dr. Mark Krekeler exceeds the scope of his expertise by offering opinions on carcinogenicity, mining standards, and regulatory processes.¹²⁶ Dr. Krekeler is qualified as to all proffered testimony.

Dr. Krekeler has a Ph.D. in Geotechnical Engineering and Earth Science and is a tenured Associate Professor in Geology.¹²⁷ Dr. Krekeler regularly teaches courses on ore deposits and mineralogy, including industrial mineralogy.¹²⁸ His curriculum includes the concepts and processes of drilling, core drilling, and methods for defining ore.¹²⁹ Dr. Krekeler has served as a consultant for various mining companies, advising regarding procedures and techniques related to mineral sampling,¹³⁰ and based on his analyses of ore minerals and waste materials.¹³¹

J&J argues that Dr. Krekeler is unqualified because he proffers medical and epidemiological testimony on the carcinogenicity of talc, asbestos, and non-asbestiform ore. J&J suggests that Dr. Krekeler provides medical inference or

¹²⁶ See Defs.’ Mem., Qualifications at 13.

¹²⁷ Expert Report of Mark Krekeler, Ph.D, Nov. 16, 2018 (“Krekeler Rep.”) at 1, attached as **Exhibit 13**.

¹²⁸ *Id.*

¹²⁹ Deposition of Mark Krekeler, Ph.D., Jan. 25, 2019 (“Krekeler Dep.”) at 326:17-327:6, attached **Exhibit 14**.

¹³⁰ Krekeler Rep. at 1.

¹³¹ *Id.*

expertise, instead of reporting facts known to geologists, like Dr. Krekeler, in the ordinary course of their work.¹³²

For example, J&J complains that Dr. Krekeler testified that arsenic and nickel are “known human carcinogen[s].”¹³³ And, J&J criticizes Dr. Krekeler’s testimony that “[a]cademic and research literature have long-recognized many toxic metals commonly found in talc as known or possible carcinogens,”¹³⁴ suggesting that an academic geologist and private sector analyst would not routinely rely on such literature. However, they certainly do,¹³⁵ and J&J’s critiques Dr. Krekeler for using reliance materials, generally accepted among geologists and used in routine practice, including in Dr. Krekeler’s academic and consulting work.¹³⁶

J&J additionally suggest that Dr. Krekeler oversteps his qualifications by opining that non-asbestiform cleavage fragments are similar to asbestos and pose the same health risks.¹³⁷ However, J&J misrepresent Dr. Krekeler’s testimony. Dr. Krekeler stated, “Notably, non-asbestiform minerals such as large crystals of tremolite or anthophyllite could be modified during processing and be turned into

¹³² Defs.’ Mem., Qualifications at 13-14.

¹³³ *Id.* at 14; (*accord* Krekeler Rep. at 6–7, 33–34.).

¹³⁴ *Id.* at 6–7.

¹³⁵ Krekeler Dep. at 324:9-324:11; 325:2-325:5 (*accord* Krekeler Rep. at 2).

¹³⁶ *Id.*

¹³⁷ See Def. Motion to Exclude Asbestos-Related Opinions, at 93.

asbestiform particles with the same health risks as asbestos, due to the size, morphology, and chemistry of the modified particles.”¹³⁸ As a mineralogist, Dr. Krekeler’s focus is on geology and mineral formation, and, as a professor, he instructs students regarding the risks and benefits of mineral extraction as well use of such minerals, which would include assessing whether minerals meet the size and shape of regulated mineral fibers, thus causing a health risk. Dr. Krekeler is not offering a medical opinion regarding non-asbestiform cleavage fragments, but an opinion as a geologist and mineralogist.

J&J next incorrectly contends that Dr. Krekeler is unqualified to testify regarding J&J’s non-compliance regarding mining standards and regulatory standards.¹³⁹ Dr. Krekeler relied on his experience and skill from both the academic and private sectors in reviewing corporate documents and corporate deposition testimony.¹⁴⁰ More specifically, Dr. Krekeler had the ability to analyze and extract data, identifying J&J’s flawed mineral screening method in powder x-ray diffraction,¹⁴¹ a method in which Dr. Krekeler has extensive knowledge, experience, and “expertise.”¹⁴² Additionally, Dr. Krekeler’s expertise allowed him to analyze

¹³⁸ Krekeler Rep. at 3–4.

¹³⁹ *Id.* at 15.

¹⁴⁰ See *id.* at 2.

¹⁴¹ Krekeler Dep. at 44:22-45:13.

¹⁴² *Id.* at 14:15-16:14.

coring, bulk chemical testing, electron microscopy, and other data. Based on his experience, Dr. Krekeler is able to identify how any of these processes were performed, and the effectiveness and limitations of such methods.¹⁴³

In Dr. Krekeler's role as a tenured Associate Professor in the Department of Geology & Environmental Earth Science, he continuously updates on the regulatory standards associated with geology and mineralogy in mining. This knowledge includes that of the heavy metals associated with talc ore designated as toxic by national and international regulatory bodies.¹⁴⁴ He has applied his knowledge of these principles as well as mining and sampling techniques as a consultant in the field, advising various mining companies specifically regarding procedures and techniques related to mineral sampling and waste materials.¹⁴⁵ Just as Dr. Krekeler has evaluated clients' compliance and advised on any systemic failures in mining processes, he identified within J&J's internal documents instances of poor quality control and review process for sampling that, despite its insufficiency, still revealed detectable asbestos.¹⁴⁶ Each of these areas of experience qualify him to opine that J&J's sampling and testing for cosmetic grade product were inadequate.¹⁴⁷

¹⁴³ *Id.* at 29:3-29:12.

¹⁴⁴ Krekeler Rep. at 6-7.

¹⁴⁵ *Id.* at 1.

¹⁴⁶ *Id.* at 39-40.

¹⁴⁷ *Id.* at 39.

Dr. Krekeler's expertise will allow him to educate a jury, as he would his students, as to procedures and techniques related to mineral sampling, extraction, and use, specifically, here, regarding talc, and its derivative constituents.

Because Dr. Krekeler possesses the knowledge, skill, experience, training, or education amounting to "specialized expertise" in the Third Circuit, he is qualified to testify in this matter concerning all proffered testimony.

F. Shawn Levy, Ph.D

J&J conditionally challenges Dr. Shawn Levy's qualifications by arguing that Dr. Levy's biological plausibility opinions "exceed his expertise."¹⁴⁸

It should be obvious that Dr. Levy is qualified to testify about biological plausibility issues. Dr. Levy has two B.S. degrees, in Biochemistry and Microbiology, and a Ph.D. in Biochemistry.¹⁴⁹ Particularly relevant to his biological plausibility qualifications, Dr. Levy's research has focused on the role of inflammation in causing ovarian cancer.¹⁵⁰ During his post-doctoral fellowship, Dr. Levy developed the first microarray designed to interrogate mitochondrial gene

¹⁴⁸ Defs.' Mem., Qualifications at 8.

¹⁴⁹ Expert Report of Shawn Levy, Ph.D, Nov. 16, 2018 ("Levy Rep.") at 1, attached as **Exhibit 15**.

¹⁵⁰ Deposition of Shawn Levy, Ph.D., Jan. 11, 2019 ("Levy Dep.") at 91:23-91:24; 92:1-92:7, attached as **Exhibit 16**.

function.¹⁵¹ He has held multiple academic appointments, including professorships in schools of molecular physiology, biomedical informatics, biological sciences, genetics, and epidemiology.¹⁵² Presently, Dr. Levy holds professorships in the Department of Genetics and Department of Epidemiology at University of Alabama—Birmingham and in the Department of Biological Sciences at University of Alabama—Huntsville.¹⁵³ Dr. Levy has served as a reviewer for many scientific journals, including *Nature Genetics*, *Science*, *Cell*, and *Genome Research*.¹⁵⁴ Additionally, he has authored over 140 peer-reviewed publications.¹⁵⁵

Dr. Levy's laboratories have used high performance genotyping and sequencing technologies to support projects, ranging from plant and animal phylogenetic studies to translational and clinical based projects.¹⁵⁶ Dr. Levy's work has included the use of genome sequencing to "identify genetic markers associated with specific health conditions," including ovarian cancer.¹⁵⁷

¹⁵¹ Levy Rep., Exhibit A (Levy CV).

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 1.

¹⁵⁵ Levy CV at 1.

¹⁵⁶ *Id.*

¹⁵⁷ Levy Rep. at 1–2.

Additionally, Dr. Levy currently is associated with the Vanderbilt Cancer Center and University of Alabama at Birmingham's Comprehensive Cancer Center, where he is involved in many of their research projects, including those involving ovarian cancer.¹⁵⁸ He additionally leads the largest genetic profiling effort for adult cancer in the nation, which includes the involvement of 15 national cancer institutes and ovarian cancer as a component of research.¹⁵⁹

J&J's suggestion that Dr. Levy only was retained to describe the role of genetics is false. Dr. Levy's testimony is also being offered "to assess whether perineal use of talcum powder products induces biologically plausible mechanism or mechanisms that results in ovarian cancer."¹⁶⁰ Dr. Levy's research has included the examination of mechanistic effects of cancer, including ovarian cancer.¹⁶¹ As such, his review of biological plausibility in this case "was a similar review" to his past research,¹⁶² and the biological plausibility mechanisms for ovarian cancer certainly are well within his expertise.

J&J suggests that Dr. Levy's singular published article concerning ovarian cancer limits his expertise, yet they disregard his past and ongoing cancer research,

¹⁵⁸ Levy Dep. at 91:4-91:9.

¹⁵⁹ *Id.* at 99:1-99:7.

¹⁶⁰ Levy Rep. at 2.

¹⁶¹ Levy Dep. at 95:21-96:4.

¹⁶² *Id.* at 96:2-96:6.

as noted above, which includes ovarian cancer, as well as past assignments with the U.S. Department of Defense, studying ovarian and breast cancer and reviewing ovarian cancer grants, specifically.¹⁶³ Dr. Levy has been, and presently is, involved in research about ovarian cancer.¹⁶⁴

J&J next argues, with no support, that Dr. Levy has no experience with talc.¹⁶⁵ Dr. Levy's opinion on the amplification effect of talc, fibrous talc, asbestos, heavy metals and fragrances is based on cell biology, of which Dr. Levy is the expert: Dr. Levy testified that the more biologically active compounds present, the more likely a biological mechanism is present.¹⁶⁶

Further, in terms of other mechanisms by which talcum powder could cause ovarian cancer, Dr. Levy testified: “[M]y research has included the role of inflammation and a number of biological processes,” which “include ...ovarian cancer.”¹⁶⁷ Prior to this litigation, Dr. Levy reviewed some of the literature concerning talcum powder and ovarian cancer, and, since, has completed a more in-depth review, including the epidemiologic literature.¹⁶⁸

¹⁶³ *Id.* at 90:20-91:9.

¹⁶⁴ Levy Rep. at 1-2; Levy Dep. at 91:4-91:9.

¹⁶⁵ See Defs.' Mem., Qualifications at 16.

¹⁶⁶ Levy Dep. at 235:9-16.

¹⁶⁷ *Id.* at 91:23-92:7.

¹⁶⁸ *Id.* at 96:7-96:21; 91:23-92:7.

Dr. Levy's expertise in this litigation will assist the jury in understanding biological plausibility based on Dr. Levy's knowledge of cancer mechanisms and genetics.¹⁶⁹

G. Anne McTiernan, MD, Ph.D.

J&J contests Dr. Anne McTiernan's qualifications by arguing that Dr. McTiernan is lacking sufficient publications and that her opinions were developed after she was retained by the PSC' counsel. J&J further argues that her opinions are outside her expertise regarding: (1) biological plausibility; and (2) talcum powder contaminants.

Dr. McTiernan is well-qualified as to all proffered testimony. She is a cancer prevention researcher and a Member in the Program in Epidemiology at the Fred Hutchinson Cancer Research Center, where she previously has served as a director in the Prevention Center.¹⁷⁰ She is also a professor in the departments of medicine and epidemiology at the University of Washington.

Dr. McTiernan has a Ph.D. in Epidemiology and a medical degree in internal medicine. For the past 25 years, she has focused on epidemiologic research, primarily in cancer and women's health. She has published over 400 scientific

¹⁶⁹ Levy Rep. at 2.

¹⁷⁰ Expert Report of Anne McTiernan, MD, Ph.D, Nov. 16, 2018 ("McTiernan Rep.") at 3, attached as **Exhibit 17**.

articles in peer-reviewed journals,¹⁷¹ including publications on gynecologic cancers, including ovarian cancer. In addition to leadership and research positions she has held with the federal government (HHS, DOD, NIH and NCI), Dr. McTiernan's work includes research for the International Association for Research in Cancer (IARC) and the World Cancer Fund.¹⁷²

In this matter, Dr. McTiernan was asked to address the question of whether perineal Talcum Powder Products use can cause ovarian cancer.¹⁷³ She conducted a systematic review and causation analysis of the association between genital use of Talcum Powder Products and the risk of developing epithelial ovarian cancer.¹⁷⁴

J&J argues to exclude the testimony of Dr. McTiernan on grounds that she "has not published any articles on the causes of ovarian cancer" and that her opinion that talcum powder use causes ovarian cancer only occurred after she was retained as an expert.¹⁷⁵ Neither of these, even if true, are necessary under the Third Circuit standards. However, J&J has mischaracterized Dr. McTiernan's experience and qualifications on these two points. *First*, Dr. McTiernan has published several

¹⁷¹ *Id.* at 3.

¹⁷² *Id.* at 4.

¹⁷³ *Id.* at 9.

¹⁷⁴ *Id.* at 7.

¹⁷⁵ Defs.' Mem., Qualifications at 17.

manuscripts on gynecologic cancer, including ovarian cancer.¹⁷⁶ J&J also disregards Dr. McTiernan's work in one of the only three cohort studies significant to this litigation. Long before Dr. McTiernan was retained, she served as Project Director at the Women's Health Initiative (WHI). In this role, Dr. McTiernan oversaw development of the protocol and procedures for ascertainment and adjudication of cancer outcomes, including ovarian cancer.¹⁷⁷

Second, Dr. McTiernan reached her opinion that perineal use of Talcum Power Products can cause ovarian cancer “after [she] conducted a full systematic review of the epidemiology data and mechanistic data, including biologic evidence, and then [...] a causal analysis.”¹⁷⁸ This litigation was also not Dr. McTiernan’s first exposure to the existing literature regarding Talcum Powder Products and ovarian cancer, as she was familiar with the articles prior to her involvement.¹⁷⁹

On this point, Dr. McTiernan has conducted extensive work, contributing to public knowledge about the potential health hazards of talcum powder. She recently presented testimony on this subject to the Congressional Subcommittee examining

¹⁷⁶ Deposition of Anne McTiernan, MD, Ph.D., Jan. 28, 2019 (“McTiernan Dep.”) at 61:22-62:5, attached as **Exhibit 18**.

¹⁷⁷ McTiernan Rep. at 5-6.

¹⁷⁸ McTiernan Dep. at 45:22-46:5.

¹⁷⁹ *Id.* at 61:12-21.

“Public Health Risk on Carcinogens and Consumer Products,”¹⁸⁰ specifically testifying as to her epidemiologic expertise in women’s cancers, including the science on Talcum Powder Products and ovarian cancer.¹⁸¹ Dr. McTiernan shared these same opinions with Health Canada, who also sought her input on this question.¹⁸²

Significantly, J&J consistently misrepresents Dr. McTiernan’s opinions and testimony. Throughout their briefing, J&J seeks to discredit Dr. McTiernan’s causality opinions, as well as the body of scientific literature. In doing so, they mischaracterize a report to which Dr. McTiernan contributed concerning diet, exercise, and nutrition. This characterization recasts what is, in reality, a narrow and limited-purpose report as a comprehensive overview of known risk factors for ovarian cancer.¹⁸³

¹⁸⁰ Testimony of Anne McTiernan, House of Representatives Subcommittee on Economic and Consumer Policy (March 12, 2019) (“Congressional Statement”), attached as **Exhibit 19**.

¹⁸¹ Having assessed and analyzed the totality of the scientific studies conducted over 40 years, she testified that women who use Talcum Powder Products have a statistically significant (22% to 31%) increased risk of developing epithelial ovarian cancer.

¹⁸² In her comments to Health Canada, Dr. McTiernan opined that the conclusions independently reached by Health Canada agree with her own. Draft Safety Assessment—Talc Public Comment to Health Canada of Anne McTiernan (February 9, 2019), attached as **Exhibit 20**.

¹⁸³ Affidavit of Anne McTiernan (May 28, 2019), attached as **Exhibit 21**.

J&J also seeks to limit Dr. McTiernan's testimony as beyond the bounds of her expertise. *First*, J&J claim that Dr. McTiernan "has no relevant qualifications" that would allow her to speak to biological plausibility in this matter.¹⁸⁴ Dr. McTiernan is a trained physician. J&J may argue the weight of this experience at trial but claiming that she has "no relevant qualifications" on this issue is ridiculous. Further, Dr. McTiernan will not offer testimony that *only* could be provided by a gynecologist, oncologist, pathologist, or cancer biologist. She has conducted an analysis befitting an expert epidemiologist and physician, focusing on assessing the body of epidemiologic literature.

J&J further argues that Dr. McTiernan is unqualified to opine that "cosmetic talc is capable of causing ovarian cancer because it is contaminated with asbestos, fibrous talc, fragrances and heavy metals such as chromium, nickel and cobalt."¹⁸⁵ Dr. McTiernan does not offer her opinions as an expert in asbestos, and her causal analysis is not dependent on the presence of asbestos in talcum powder. Dr. McTiernan included asbestos in her analysis because she "would often see the potential for asbestos being included in Talcum Powder Products, so [she] wanted to include that as one possible mechanism, especially given that asbestos is a known carcinogen," but her causal analysis was only done in regards to Talcum Powder

¹⁸⁴ Defs.' Mem., Qualifications at 18.

¹⁸⁵ *Id.* at 18-19.

Products as a whole.¹⁸⁶ The PSC response is also addressed in the above section on asbestos and other contaminants.

H. Patricia Moorman, Ph.D., MSPH

J&J contests Dr. Patricia Moorman's qualifications by arguing that Dr. Moorman's opinions exceed her expertise as to two primary issues: (1) biological plausibility; and (2) the presence of asbestos, heavy metals, and fragrances in talcum powder.¹⁸⁷ Dr. Moorman is qualified as to all proffered testimony.

Dr. Moorman is a tenured professor at Duke University School of Medicine, and she participates in the Cancer Control and Population Sciences Program at Duke Cancer Institute, where she serves as Director of Clinical Research.¹⁸⁸ She has an undergraduate degree in pharmacy, graduate degrees in epidemiological studies and public health.¹⁸⁹ She has experience as a Research Scientist at Yale University, School of Public Health.

For more than 25 years, Dr. Moorman has conducted epidemiological research, publishing on women's health issues, including ovarian cancer and ovarian

¹⁸⁶ McTiernan Dep. at 269:9-270:1.

¹⁸⁷ See Defs.' Mem., Qualifications at 20.

¹⁸⁸ Expert Report of Patricia Moorman, MSPH, Ph.D., Nov. 6, 2018 ("Moorman Rep.") at 3-4, attached as **Exhibit 22**.

¹⁸⁹ *Id.* at 3.

function.¹⁹⁰ Among these studies, Dr. Moorman has published case-control studies concerning ovarian cancer and a cohort study designed to examine ovarian failure.¹⁹¹ In 2016 (prior to her involvement in this litigation), Dr. Moorman's study team published a peer-reviewed paper, analyzing the relationship between talcum powder exposure and ovarian cancer.¹⁹² Dr. Moorman authored over 130 publications, *more than 50 of which relate directly to ovarian cancer.*¹⁹³

Dr. Moorman's extensive background in epidemiology and women's health issues, including ovarian cancer, make her more than qualified to offer a biological plausibility opinion. One of the nine factors set forth by Bradford Hill is biological plausibility, so naturally, she assessed it. Dr. Moorman testified that she incorporates the Bradford Hill methodology, including "biological plausibility" "into essentially every paper that [she] write[s]."¹⁹⁴

J&J's argument that Dr. Moorman is neither a cancer biologist nor a toxicity studies expert does not undermine Dr. Moorman's extensive experience in ovarian

¹⁹⁰ *Id.* at 3–4.

¹⁹¹ *Id.* at 4.

¹⁹² *Id.* at 5.

¹⁹³ *Id.* Additionally, prior to her 2016 peer-reviewed publication, Dr. Moorman participated as an investigator on the North Carolina Ovarian Cancer Study. Presently and since 2016, Dr. Moorman is an investigator for the Ovarian Cancer in Women of African Ancestry (OWCAA) consortium.

¹⁹⁴ Deposition of Patricia G. Moorman, M.S.P.H., Ph.D. (Mar. 12, 2018) ("Moorman Dep. 2") at 358:16-25, attached as **Exhibit 23**.

cancer research, spanning more than 25 years and producing more than 50 studies reviewing ovarian cancer, including its causes.¹⁹⁵

Dr. Moorman is particularly qualified to offer opinions on biological plausibility because she also has addressed biological plausibility issues in her peer-reviewed, published articles. Dr. Moorman's 2016 published peer-reviewed paper specifically refers to inflammation as a potential mechanism by which talcum powder can cause ovarian cancer,¹⁹⁶ and addressed biological plausibility: "talc-containing powders may promote cancer development through local inflammation, increased rates of cell division and DNA repair[,] increased oxidative stress and increased cytokine levels."¹⁹⁷

J&J mischaracterizes Dr. Moorman's testimony regarding the thoroughness of her literature review. She testified that she, "tried" and read every article on migration of which she was aware, but that she "cannot say with 100 percent certainty that [she] identified every single study related to migration."¹⁹⁸ That should be more than sufficient to assess biological plausibility.

¹⁹⁵ Moorman Rep. at 3–5.

¹⁹⁶ Moorman Dep. 2 at 239:8-240:2.

¹⁹⁷ *Id.*; see also J.M. Schildkraut, et al., *Cancer, Epidemiology, Biomarkers, & Prevention, Association Between Body Powder Use and Ovarian Cancer Epidemiology Study (AACES)*, 25(10), 1411 (Oct. 2016), attached as **Exhibit 24**.

¹⁹⁸ Deposition of Patricia G. Moorman, M.S.P.H., Ph.D. (Jan. 25, 2019) ("Moorman Dep. 1") at 58:25-59:16, attached at **Exhibit 25**.

J&J's next challenge to Dr. Moorman's qualification regards the existence of evidence addressing the presence of asbestos, heavy metals, and fragrances in talcum powder.¹⁹⁹ Dr. Moorman is experienced in the review of documents, including those outside the literature.²⁰⁰ She specifically testified, "... the gist of my opinions are based on talcum powder products and whatever constituents are in there; so, talc, asbestos, any fragrances or other contaminants that may be in there. *So its based on the product.*"²⁰¹ To that, she only adds that the presence of asbestos, (and other contaminants) in talc would "contribute" further to biological plausibility, "that this is *another* potential constituent of the talcum powder product that could contribute to ovarian cancer risk."²⁰² This testimony is clearly within the scope of her expertise as an epidemiologist.

The PSC's response is addressed further above in the general section on asbestos and other contaminants.

¹⁹⁹ Defs.' Mem., Qualifications at 20.

²⁰⁰ Moorman Dep. 1 at 126:22-127:16. For instance, Dr. Moorman testified to conducting a systemic review by which she examined company documents for relevance in analyzing the plausible relationship between oral contraception and cancer risk.

²⁰¹ *Id.* at 119:21-25.

²⁰² *Id.* at 117:7-14.

I. Laura Plunkett, Ph.D., DABT

J&J contests Dr. Laura Plunkett's qualifications by questioning her expertise in toxicology and arguing that her opinions concerning biological plausibility and talc contamination are beyond the scope of her expertise.²⁰³ Dr. Plunkett is well-qualified as to all proffered testimony and specifically to opine "that the weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women."²⁰⁴

Laura M. Plunkett, Ph.D., DABT has advanced training as a pharmacologist and toxicologist and through that training has unique expertise in pharmacokinetics. She received her Ph.D. in Pharmacology and is Board Certified in Toxicology (1993–present).²⁰⁵ Dr. Plunkett has worked as an industry consultant and regulatory expert for approximately 30 years, including as a consultant to pharmaceutical companies in the areas of pharmacology, toxicology, human health risk assessment, and regulatory strategy and FDA regulatory compliance.²⁰⁶ Dr. Plunkett also

²⁰³ See Defs.' Mem., Qualifications at 23.

²⁰⁴ Expert Report of Laura Plunkett, Ph.D., DABT, Nov. 16, 2018 ("Plunkett Rep.") at 77, attached as **Exhibit 26**.

²⁰⁵ Plunkett Rep., Exhibit A (Plunkett CV) at 3.

²⁰⁶ *Id.* at 1-2.

reviewed and assessed the safety of talc as used in condoms, which are regulated as medical devices.²⁰⁷

Despite J&J's claim, Dr. Plunkett does not just "purport[] to be a toxicologist,"²⁰⁸ she is one. Dr. Plunkett has been board certified as a Diplomate of the American Board of Toxicology since 1993.²⁰⁹ To do so, Dr. Plunkett had to complete a comprehensive certification examination on principles of toxicology and has had to undergo recertification every five years.²¹⁰ According to the National Institute of Environmental Health Sciences, "[t]his means that the person has passed several tests and is certified by one of the world's largest organizations in general toxicology, the American Board of Toxicology (ABT)."²¹¹ Dr. Plunkett is a member of the Society of Toxicology and the American College of Toxicology.²¹² She has written dozens of peer-reviewed articles and book chapters and presented at numerous conferences and seminars on issues related to pharmacology, toxicology,

²⁰⁷ Plunkett Rep. at 5.

²⁰⁸ Defs.' Mem., Qualifications at 23.

²⁰⁹ Plunkett CV at 3.

²¹⁰ See, American Board of Toxicology, <https://www.abtox.org/about-abt/>, <https://www.abtox.org/candidates/overview/>.

²¹¹ See, National Institute of Environmental Health Sciences, <https://www.niehs.nih.gov/health/topics/science/toxicology/index.cfm>.

²¹² Plunkett CV at 3.

and pharmacokinetics.²¹³ These articles include animal (preclinical), human, and *in vitro* studies. In addition to her research and publications, Dr. Plunkett was an Assistant Professor of Pharmacology and Toxicology from 1986–1989.²¹⁴

Similarly, J&J takes an unsupported jab at her professional background by characterizing Dr. Plunkett as a “litigation pharmacologist,”²¹⁵ without challenging her qualifications as a pharmacologist and despite the decades Dr. Plunkett has spent working in the field.²¹⁶

J&J claims that Dr. Plunkett should be precluded from testifying about biological plausibility in part because she “ma[de] clear at her deposition that she is ‘not doing general causation in the MDL.’”²¹⁷ This does not accurately reflect her testimony. Dr. Plunkett testified that her role in this litigation is to provide a risk assessment, which is different from a general causation analysis.²¹⁸ However, “the types of information that are considered may overlap between those two [...].”²¹⁹ As part of this risk assessment, Dr. Plunkett provides “opinions on certain aspects of the

²¹³ *Id.* at 4-15.

²¹⁴ *Id.* at 2.

²¹⁵ Defs.’ Mem., Qualifications at 23.

²¹⁶ Plunkett Rep. at 3-4.

²¹⁷ Defs.’ Mem., Qualifications at 23.

²¹⁸ Deposition of Laura Plunkett, Ph.D., DABT (Dec. 19, 2018) (“Plunkett Dep.”) at 35:3-37:19, attached as **Exhibit 27**.

²¹⁹ *Id.*

cause and effect relationship,” including biologic plausibility and “underlying knowledge about different toxicities of the compounds.”²²⁰

J&J next argues that Dr. Plunkett’s biological plausibility analysis is “divorced” from the expertise she described at her deposition.²²¹ Dr. Plunkett is qualified as a pharmacologist and toxicologist to explore biologic plausibility. Dr. Plunkett explained that she needs “to understand whether there’s a biologic mechanism that makes sense[]” and whether “exposure could lead to this response.”²²² Dr. Plunkett’s “typical[]” process is to analyze data according to the Bradford Hill considerations.²²³

J&J also seek to exclude Dr. Plunkett’s testimony on biological plausibility and the presence of contaminants based on her lack of publications on these topics.²²⁴ J&J cites no caselaw that publication on a particular topic is a prerequisite for an expert to be qualified to testify about that topic.

²²⁰ Plunkett Dep. at 33:19-34:9.

²²¹ Defs.’ Mem., Qualifications at 24.

²²² Plunkett Dep. at 195:15-20.

²²³ *Id.* at 35:3-37:19.

²²⁴ Defs.’ Mem., Qualifications at 23.

J. Ghassan Saed, Ph.D.

Dr. Saed is an Associate Professor with tenure at Wayne State University where he is the Director of Ovarian Cancer Research.²²⁵ He is a faculty member in the Departments of Obstetrics & Gynecology, Cell Biology, and Anatomy & Physiology at Wayne State School of Medicine, and is a Member of the Karmanos Cancer Institute, Molecular Biology and Genetics Program.²²⁶ As the Director of Ovarian Cancer Research, Dr. Saed's laboratory investigates the role of oxidative stress in the pathogenesis of ovarian cancer. His research in ovarian cancer has resulted in the identification of biomarkers for assessing the progression and metastasis of ovarian cancer.²²⁷

Dr. Saed has been the recipient of national and international grants and contracts from prestigious organizations and has been a prolific publisher and presenter at scientific meetings. He has been an author on more than 130 original studies published in peer-reviewed journals in addition to writing review articles and book chapters.²²⁸ Dr. Saed recently published a review article in the journal *Gynecologic Oncology* titled "Updates of the role of oxidative stress in the

²²⁵ See Expert Report of Dr. Ghassan Saed, Nov. 16, 2018 ("Saed Rep."), at 2, attached as **Exhibit 28**.

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Id.* at 3.

pathogenesis of ovarian cancer.”²²⁹ In addition, his recent research related to talcum powder products, inflammation and oxidative stress has been peer-reviewed and accepted for publication in *Reproductive Sciences*.²³⁰ As Dr. Saed has stated, this is what he has done “for the last 30 years, ovarian cancer, oxidative stress, and inflammation.”²³¹ Dr. Saed’s “specialty is anything that induces inflammation and oxidative stress that is linked to ovarian cancer.”²³²

J&J challenges the qualifications of Dr. Saed to opine on talcum powder and ovarian cancer because he is not “a physician [or an] OB-GYN oncologist” and can’t diagnose or determine the cause of ovarian cancer.²³³ However, Dr. Saed is not offering opinions on the diagnosis. As reflected above, in his *curriculum vitae*, and his publication record, Dr. Saed is an established translational researcher, and his research interest currently focuses on the identification of biomarkers for the early detection of ovarian cancer, and the characterization of novel therapeutic targets for the treatment of ovarian cancer. Dr. Saed and his staff would be expected to and do

²²⁹ *Id.*

²³⁰ N.M. Fletcher, *et al.*, *Reproductive Sciences, Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer*, 20(10), 1–11 (2019).

²³¹ See Deposition of Ghassan Saed, Ph.D., Jan. 23, 2019 (“Saed Dep.”) at 27:4-6, attached as **Exhibit 29**.

²³² *Id.* at 27:10-11; 30:11-13 (“anything that causes inflammation, redox imbalance, is linked to increased risk of ovarian cancer. This is the core of my work.”).

²³³ See Defs.’ Mem., Qualifications at 24.

have the expertise and experience to conduct the experiments that form the basis of his talcum powder research and opinions offered in this case.

J&J's further argument that Dr. Saed is not qualified to offer his opinions because he has never examined the effect of particulate exposure on cells in vitro is a red herring. The tests that were used during Dr. Saed's experiments are broadly used and scientifically acceptable. They have been used by Dr. Saed in his lab for decades and he has authored and published more than 130 studies in peer reviewed journals based upon his work. As addressed in further detail in *The PSC's Memorandum of Law in Opposition to Defendant Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion to Exclude Expert Opinions of Ghassan Saed*, which arguments are adopted herein by reference, Dr. Saed used proper control methods and did not have any methodological shortcomings. The quality of work performed by Dr. Saed is bolstered by the fact that his work has been the subject of four abstracts, published in peer-reviewed scientific journals, and presented at prestigious medical conferences. All of the aforementioned required peer review of his methodology by multiple experts in the field.

Lastly, contrary to J&J's assertion, Dr. Saed does not express opinions on epidemiology studies. Instead, as noted at his deposition, Dr. Saed reviewed and relies upon all forms of studies in forming opinions and in guiding his work. "I always

review literature, this is my job, that's what I do for a living, I review literature every single day.”²³⁴

K. Jack Siemiatycki, Ph.D.

J&J contests Dr. Jack Siemiatycki’s qualifications by arguing that his opinions on biological plausibility and the presence of contaminants in Talcum Powder Products are beyond the scope of his expertise.²³⁵ Dr. Siemiatycki is well-qualified as to all proffered general causation testimony, including biological plausibility. Also, when his actual opinions about talcum powder constituents are understood, it will be clear that he is qualified to offer those opinions too.

Dr. Siemiatycki is qualified to offer all general causation opinions. He is a tenured Professor of epidemiology at the University of Montreal and Adjunct Professor of epidemiology at McGill University.²³⁶ He holds the Guzzo-Cancer Research Society Chair in Environment and Cancer and is an elected fellow of the Canadian Academy of Health Sciences. In recognition of his exemplary work in epidemiology and statistics he was awarded a lifetime achievement award by the Canadian Society for Epidemiology and Biostatistics. He has been invited to serve on over 160 Boards, scientific councils, and expert panels for a host of governments,

²³⁴ Saed Dep. at 32:18-20.

²³⁵ See Defs.’ Mem., Qualifications at 26.

²³⁶ Expert Report of Jack Siemiatycki, MSc, Ph.D, Nov. 16, 2018 (“Siemiatycki Rep.”), Exhibit A (Siemiatycki CV), attached as **Exhibit 30**.

universities, and research agencies (Canadian and American NCI). His leadership positions include the presidency of the Canadian Society for Epidemiology and Biostatistics and the Board of the American College of Epidemiology.²³⁷

Dr. Siemiatycki has devoted most of his research career to investigating links between environmental, occupational and lifestyle factors and various types of cancer. This “research has been both substantive – namely, looking at particular factors and their possible relationship to particular cancers – and methodological – namely, exploring how to evaluate and enhance the validity of epidemiologic research through various prisms: study design, data collection methods and statistical analysis.”²³⁸ In addition to serving as a reviewer for approximately 20 journals, he has served as the associate editor of the *American Journal of Epidemiology* and the *International Journal of Environmental Health*.

Dr. Siemiatycki’s long-standing association with the International Agency for Research on Cancer (IARC) began in 1977. He has since served as a member and elected chairman of its Scientific Council. Prior to his retention in this litigation, he chaired the 2006 IARC Monograph panel evaluation of the relative carcinogenicity of carbon black, titanium dioxide, and non-asbestiform talc.²³⁹ Having considered

²³⁷ Siemiatycki Rep. at 1-2

²³⁸ *Id.* at 1.

²³⁹ *Id.* at 3, 23-24.

data provided through 2006, this panel classified Talc as a 2B possible carcinogen. Subsequent to the IARC meeting, and prior to his retention as an expert, Dr. Siemiatycki co-conducted and published a meta-analysis of studies on talcum powder products and ovarian cancer available to the IARC Working Group in 2007.²⁴⁰ He has published more than 250 peer-reviewed articles.

Dr. Siemiatycki reviewed all available, relevant scientific evidence to formulate his general causation opinions.²⁴¹ He systematically selected and assessed all epidemiological published studies, meta-analyses, experimental toxicology, molecular biology, mechanistic studies, and the IARC Monograph. His expert judgment was based on assessing and weighing the totality of the data.²⁴²

J&J does not argue that Dr. Siemiatycki is not qualified to opine on biological plausibility or contaminants in talcum powder products so much as they claim (incorrectly) that he admits to not being qualified to offer those opinions.²⁴³ While he may not be qualified to determine the “most likely mechanism by which talc could cause ovarian cancer,”²⁴⁴ Dr. Siemiatycki testified that he can evaluate potential

²⁴⁰ See Langseth, H., S. E. Hankinson, J. Siemiatycki and E. Weiderpass (2008), Perineal use of talc and risk of ovarian cancer. *Journal of Epidemiology & Community Health* 62(4): 358-360, attached as **Exhibit 31**.

²⁴¹ Siemiatycki Rep. at 1.

²⁴² *Id.* at 4-5, 18-22.

²⁴³ See Defs.’ Mem., Qualifications at 26.

²⁴⁴ See *id.*

biologically plausible mechanisms “on the basis of [his] reading of literature concerning that issue.”²⁴⁵ Dr. Siemiatycki is well-qualified as an epidemiologist to evaluate the literature to form an assessment of biological plausibility. In formulating his opinions, Dr. Siemiatycki “employed the same scientific methodology and rigor that [he uses] in [his] research, in [his] publications, and in the consulting and advising that [he carries] out on behalf of governments, public health agencies, and research institutes.”²⁴⁶ The PSC’s have addressed this further above in the general section on biological plausibility.

J&J further argues that Dr. Siemiatycki is unqualified to opine “whether there ‘are in fact contaminants like asbestos or heavy metals in Johnson & Johnson’s talcum powder products’” because he admits to not being “an expert in the composition of talc.”²⁴⁷ The PSC’s response is addressed above in the general section on asbestos and other contaminants.²⁴⁸

²⁴⁵ Deposition of Jack Siemiatycki, MSc, Ph.D., Jan. 31, 2019 (“Siemiatycki Dep.”) at 331:10-19, attached as **Exhibit 32**.

²⁴⁶ Siemiatycki Rep. at 4-5.

²⁴⁷ See Defs.’ Mem., Qualifications at 26.

²⁴⁸ Furthermore, his causal analysis is not dependent upon the presence of contaminants in Talcum Powder Products. Dr. Siemiatycki does not opine that cosmetic talc is capable of causing ovarian cancer *only because* it is contaminated. He testified that he reviewed the information he was provided in the fields of toxicology, talc composition and biological mechanism, took note of the types of evidence that are available in those domains, and used them in considering biological plausibility. Siemiatycki Dep. at 75:6-22. “Those areas of evidence did not in any

L. Sonal Singh, MD, MPH

J&J contests Dr. Sonal Singh's qualifications by arguing that he "has no prior experience investigating the relationship between talc and ovarian cancer and has never published on the issue."²⁴⁹ They further posit that his opinions on biological mechanisms and asbestos in talcum powder products are beyond the scope of his expertise.²⁵⁰ Dr. Singh is well-qualified as to all proffered testimony.

Specifically, Dr. Singh opines, after his systematic review of the literature, that there is a statistically significant increased risk of ovarian cancer with talcum powder products and that there is strong evidence that talcum powder products can reach the fallopian tubes and ovaries and can induce ovarian cancer through established mechanisms.²⁵¹

Dr. Singh is an Associate Professor at the Meyers Primary Care Institute, with a joint appointment at the University of Massachusetts Medical School, Massachusetts.²⁵² He has lengthy academic credentials, serving as an Assistant Professor of Medicine at Wake Forest University, before receiving a joint

way influence [his] opinions about the strength and consistency [...] of the epidemiological evidence." *Id.*

²⁴⁹ *Id.* at 28.

²⁵⁰ See Defs.' Mem., Qualifications at 28-30.

²⁵¹ Expert Report of Sonal Singh, MD, MPH, Nov. 16, 2018 ("Singh Rep.") at 19, attached as **Exhibit 33**.

²⁵² See generally Singh Rep., Exhibit A (Singh CV); Singh Rep. at 3-5.

appointment as an Assistant Professor of Epidemiology. He was an Assistant Professor at Johns Hopkins University as a recipient of the NIH Johns Hopkins Clinical Research Scholars Award in 2009.²⁵³

Dr. Singh has served as an advisor to the World Bank, World Health Organization (WHO), International Agency for Research on Cancer (IARC) and various pharmaceutical firms. He was part of a WHO-IARC panel which evaluated the carcinogenicity of various drugs and herbal products.²⁵⁴

He is the recipient of numerous awards including the prestigious Johns Hopkins Clinical Research Scholars Award and the Tinsley R. Harrison Master Teachers Award. He also serves as a peer reviewer for more than 50 journals and serves on multiple editorial boards. Dr. Singh has conducted several epidemiological studies, systematic reviews and meta-analysis featured in prominent medical journals. He has authored or co-authored more than 100 original peer-reviewed scientific articles, and his work has been cited more than 13,000 times.

Dr. Singh was asked to review the scientific evidence and analyze the epidemiological data and, based on these data and other relevant evidence, to provide

²⁵³ Dr. Singh held joint appointments in the Department of International Health and Health Policy and Managements and served as the Associate Director at the Center for Drug Safety and Effectiveness at Johns Hopkins University until 2016.

²⁵⁴ His research has been funded by the Food and Drug Administration, the Agency for Health Care Research and Quality, the National Institute of Health and the Patient Centered Outcomes Research Institute.

his professional opinion about whether talcum powder products are causally related to ovarian cancer.²⁵⁵ Dr. Singh conducted his own systematic review of the epidemiological literature and the cumulative body of evidence which serves as the basis upon which he provides his opinions.²⁵⁶

J&J conditionally argues to exclude Dr. Singh on grounds that he has not previously investigated the relationship between talcum powder and ovarian cancer and has not published on the issue.²⁵⁷ The PSC has addressed this above in the general section on conditional arguments.

While Dr. Singh has not yet published literature on Talcum Powder Products causing ovarian cancer, he testified that it is not a theory of his own making, unsupported in existing literature, as there have been more than 30 studies conducted on the issue.²⁵⁸ Dr. Singh “evaluated the epidemiologic studies, which show a causal link between talc and ovarian cancer, and several other investigators [...] provided evidence [...] of talc-induced [...] migration.”²⁵⁹

²⁵⁵ Singh Rep. at 3.

²⁵⁶ *Id.*

²⁵⁷ See Defs.’ Mem., Qualifications, at 28.

²⁵⁸ See Deposition of Sonal Singh, MD, MPH, Jan. 16, 2019 (“Singh Dep.”) at 84:10-19, attached as **Exhibit 34**.

²⁵⁹ *Id.* at 85:9-22.

Despite J&J’ representations, Dr. Singh did not testify that he was not qualified to opine about the existence of the biologically plausible mechanism based on the universe of relevant data and published literature.²⁶⁰ He “provide[s] [his] own opinion” on biologic plausibility given his interpretation of the evidence.²⁶¹ For instance, Dr. Singh may defer to Dr. Saed’s expertise on ovarian cancer pathogenesis, but his role as an epidemiologist is to “look[] for evidence for or against whether information [...] induces or reduces ovarian cancer.”²⁶² Similarly, Dr. Singh is not offering an interpretation of the evidence to say that it is sufficiently proven that “talc is an established mutagen and [...] whether it’s a genotoxic or nongenotoxic carcinogen,” rather, he is looking for evidence “for or against biologic plausibility mechanisms.”²⁶³

J&J further challenges Dr. Singh’s qualifications as to opinions regarding asbestos and other talcum powder constituents.²⁶⁴ Importantly, Dr. Singh reports that he has reviewed evidence that “talcum powder products contain asbestos, fibrous talc, heavy metals such as cobalt, chromium, nickel, and various fragrance

²⁶⁰ *Id.* at 188:22-189:3.

²⁶¹ *Id.* at 188:10-13.

²⁶² *Id.*

²⁶³ *Id.* at 322:5-17.

²⁶⁴ See Defs.’ Mem., Qualifications, at 29-30.

chemicals.”²⁶⁵ The PSC’s response is addressed above in the general section on asbestos and other contaminants.²⁶⁶

M. Rebecca Smith-Bindman, MD

J&J contests Dr. Rebecca Smith-Bindman’s opinions by arguing about her lack of exposure to talcum powder and ovarian cancer research prior to this litigation.²⁶⁷ They further challenge her opinions on biological plausibility and talcum powder contaminants as beyond the scope of her expertise.²⁶⁸ Dr. Smith-Bindman is well-qualified as to all proffered testimony. Specifically, she is qualified to opine that substantial evidence supports a causal association between ovarian cancer and genital exposure to talcum powder products.

Dr. Rebecca Smith-Bindman is a Professor in multiple departments at the University of California San Francisco (UCSF) School of Medicine. She graduated from Princeton University and attended UCSF medical school. Her subsequent training included an internship, radiology residency, clinical fellowship in women’s health and a research fellowship in epidemiology and biostatistics.

²⁶⁵ Singh Rep. at 14.

²⁶⁶ Of note, his causal analysis is not dependent upon the presence of those contaminants. He testified that he “arrived at [his] causal opinion independent of [...] presence of asbestos or [...] his understanding of the constituents.” Singh Dep. at 270:24-271:12.

²⁶⁷ See Defs.’ Mem., Qualifications at 30-31.

²⁶⁸ See *id.* at 31-33.

Dr. Smith-Bindman is an academic clinician-scientist involved in patient care, epidemiological research, and teaching in the UCSF School of Medicine and Department of Epidemiology and Biostatistics. Her research expertise is in epidemiology, outcomes research, comparative effectiveness, health services research, and dissemination and implementation sciences.

Several of Dr. Smith-Bindman published studies have been systematic, meta-analytic, quantitative reviews of the published literature. Her systematic reviews focused on the diagnoses of endometrial cancer, breast cancer, and a range of birth defects. Many of these reviews were published in prestigious medical journals. In addition, Dr. Smith-Bindman has expertise in a range of research study designs, including many that addressed causation and cancer risk.²⁶⁹

J&J argues to exclude the report and testimony of Dr. Smith-Bindman because she “had not done any work with respect to talc or its purported connection with ovarian cancer” before this litigation.²⁷⁰ The PSC’ response is addressed above in the general section on conditional arguments.²⁷¹

²⁶⁹ See generally Expert Report of Rebecca Smith-Bindman, MD, Nov. 16, 2018 (“Smith-Bindman Rep.”), Exhibit A (Smith-Bindman CV), attached as **Exhibit 35**.

²⁷⁰ Defs.’ Mem., Qualifications at 30-31.

²⁷¹ Additionally, Dr. Smith-Bindman views this as a clear advantage, allowing objectivity in her opinions in this litigation. In her words, “Prior to providing my opinions on the association between talcum powder products and ovarian cancer, I had not reviewed the relevant literature and had not published in this area. As a result, I brought an unbiased perspective to my review.” Smith-Bindman Rep. at 8.

While this litigation might be the first time Dr. Smith-Bindman conducted a systematic review of the literature specifically pertaining to talcum powder and ovarian cancer this is not her first experience with ovarian cancer. “Much of [her] research is in women’s health, including diagnoses of cancers such as ovarian, endometrial, thyroid and breast.”²⁷² Prior to the litigation, she “led many large, multi-institutional research projects” that “are typically collaborative, involving researchers and clinicians with diverse expertise [...].”²⁷³ In her work as a “prolific researcher,” Dr. Smith Bindman “led projects funded by more than 50 million dollars in research grants—entirely focused on cancer diagnosis and prediction” and has been extensively “published in the most prestigious medical journals.”²⁷⁴ Significantly, she was lead author on a 2019 study published in *JAMA Internal Medicine*²⁷⁵ reporting diagnosis of ovarian cancer by histologic subtype.

J&J further seek to limit the testimony of Dr. Smith-Bindman where they claim she opines beyond the bounds of her expertise. First, J&J claim that Dr. Smith-Bindman is “plainly unqualified” as an epidemiologist to testify about biological

²⁷² *Id.* at 6.

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ Titled *Risk of Malignant Ovarian Cancer Based on Ultrasonography Findings in a Large Unselected Population.*

plausibility.²⁷⁶ It makes sense that they could not otherwise find support for this argument because analyzing biological plausibility is an integral element of the Bradford Hill aspects of causal inference for epidemiological data.²⁷⁷ The PSC's further response is addressed above in the general section on biological plausibility.

Despite J&J' claims, Dr. Smith-Bindman does not admit that her opinions on biological mechanisms fall outside of the scope of her expertise. In fact, Dr. Smith-Bindman testified: "I'm knowledgeable about the biological mechanism of cancer as a scientist, as a physician, as a cancer epidemiologist."²⁷⁸ As a clinical radiologist specializing in women's health, Dr. Smith-Bindman also has direct experience demonstrating the potential for the migration and transport of substances through the genital tract.²⁷⁹

J&J challenges Dr. Smith-Bindman's qualifications to offer opinions regarding asbestos and other constituents of talcum powder. The PSC's response is addressed above in the general section on asbestos and other contaminants. Notably, Dr. Smith-Bindman clarifies that she is an expert on the health effects of asbestos,

²⁷⁶ Defs.' Mem., Qualifications, at 31.

²⁷⁷ Smith-Bindman Rep. at 40.

²⁷⁸ Deposition of Rebecca Smith-Bindman, MD, Feb. 7, 2019 and Feb. 8, 2019 at 285:4-9, attached as **Exhibit 36**.

²⁷⁹ *Id.* at 363:12-21.

testifying that “[t]he question is about asbestos, in general, and “she considers herself” an expert on the health effects of asbestos.”²⁸⁰

N. Judith Zelikoff, Ph.D.

J&J conditionally contests Dr. Judith Zelikoff’s qualifications by arguing that she does “not have a background in talc and ovarian cancer” and that her fragrance and asbestos-related opinions are beyond her expertise.²⁸¹ Dr. Zelikoff is qualified as to all proffered testimony and specifically to opine that that “[t]he ...evidence of the presence of asbestos and fibrous talc in talcum powder products provides a biologically plausible explanation for the increased risk of ovarian cancer associated with the perineal use of talcum powder products.”²⁸²

Dr. Zelikoff received her Ph.D. in Experimental Pathology and Immunology and her post-doctoral training in toxicology at the NYU School of Medicine.²⁸³ She is currently a tenured professor in Toxicology at NYU and the Director of the Community Engagement Core as part of the National Institute of Environmental Health Science Center of Excellence.²⁸⁴

²⁸⁰ *Id.* at 22:12-19.

²⁸¹ See Defs.’ Mem., Qualifications, at 34, 36.

²⁸² Expert Report of Judith Zelikoff, Ph.D, Nov. 16, 2018 (“Zelikoff Rep.”) at 8, attached at **Exhibit 37**.

²⁸³ Zelikoff Rep., Exhibit A (Zelikoff CV); Zelikoff Rep. at 1.

²⁸⁴ Zelikoff Rep. at 1.

In the field of toxicology, Dr. Zelikoff has served on NIH Study Sections, the United Nations Environmental Programme, NASA boards, and National Academy of Science Panels, as well as Environmental Protection Agency study sections and advisory boards dealing with topics such as toxic effects of metals.²⁸⁵ She served as a member of the NTP (National Toxicology Program) board of advisors,²⁸⁶ where she collaborated to determine the carcinogenicity of specific compounds. She has over 125 publications and book chapters on immunotoxicology, toxicology, metal toxicology, and developmental and reproductive toxicology on topics including inhaled metals, nanomaterials, mixtures, dusts and tobacco and nicotine toxicology.²⁸⁷

J&J argues to exclude the testimony of Dr. Zelikoff on the narrow grounds that she did not have more in-depth knowledge of talcum powder and ovarian cancer prior to being retained in this litigation.²⁸⁸ The PSC' response is addressed above in the general section on conditional arguments.²⁸⁹

²⁸⁵ *Id.*

²⁸⁶ Zelikoff CV at 22; Zelikoff Rep. at 1.

²⁸⁷ Zeliokff CV at 4-15; Zelikoff Rep. at 1.

²⁸⁸ Defs.' Mem., Qualifications, at 33-34.

²⁸⁹ Additionally, Dr. Zelikoff does not offer testimony or opinions that are outside of her review of the scientific literature. For instance, when asked about "the number of particles of talc necessary to start the biological process," she testified that the answer was "not in the scientific literature" and did not opine beyond her systematic review of the relevant scientific literature. Deposition of Judith Zelikoff Ph.D., Jan.

J&J has failed to accurately present Dr. Zelikoff's qualifications on talcum powder and ovarian cancer. Dr. Zelikoff is an "expert in toxicology of environmental chemicals, including mixtures, including fibers, including particles, including talc."²⁹⁰ She conducted a review of scientific literature to determine "whether there is a biologically plausible explanation for the increased risk of ovarian cancer with the perineal use of talcum powder products."²⁹¹ J&J highlights that Dr. Zelikoff's prior knowledge of talcum powder and ovarian cancer was "superficial," ignoring that she meant that she was not aware of those subjects "to the depth that [she is] aware of the issue currently."²⁹²

In her analysis, Dr. Zelikoff "considered the totality of the evidence," reviewing "the genital use of the talcum powder products, the routes of exposure by which talcum powder could reach the ovaries, the composition of the talcum powder products, the biological and toxicological effects of talcum powder, and the potential

21, 2019 ("Zelikoff Dep.") at 266:10-15, attached as **Exhibit 38**. Dr. Zelikoff does not offer opinions about medical causation that may require prior knowledge in the areas of talcum powder and ovarian cancer. *Id.* at 130:22-131:6. Instead, she provides an assessment of the biological plausibility of the "causation of talc for ovarian cancer." *Id.* at 72:23-73:7. During her deposition, Dr. Zelikoff continuously confirmed for defense counsel that her "opinion is based on biological plausibility." *Id.* at 189:2-15.

²⁹⁰ *Id.* at 490:21-491:6.

²⁹¹ Zelikoff Rep. at 2.

²⁹² Zelikoff Dep. at 22:18-22.

mechanisms of carcinogenesis.”²⁹³ Dr. Dr. Zelikoff applies the “same standard for assessing biologic plausibility” here as she does in her work at NYU.²⁹⁴ As a member of the National Toxicology Program Board of Scientific Advisors, she “reviewed documents and provided ...guidance on the toxicity of various chemicals ...[including] the carcinogenicity of specific compounds.”²⁹⁵

J&J also seeks to exclude Dr. Zelikoff’s testimony on the presence of fragrances and asbestos in Talcum Powder Products giving support to a biologically plausible mechanism, arguing that “these opinions are far afield from her area of expertise.”²⁹⁶ The PSC’s response is addressed above in the general section on asbestos and other contaminants.

By the nature of her profession, Dr. Zelikoff “can review chemicals and make a decision or assess their toxicity based on outcomes,” including chemicals in fragrances.²⁹⁷ Furthermore, “a toxicologist should be able to go into the literature and have a greater knowledge than most people” in researching chemicals.²⁹⁸ Dr. Zelikoff’s background includes specific experience with fragrances and asbestos,

²⁹³ Zelikoff Rep. at 2.

²⁹⁴ Zelikoff Dep. at 69:13-17.

²⁹⁵ Zelikoff Rep. at 1.

²⁹⁶ Defs.’ Mem., Qualifications at 35.

²⁹⁷ Zelikoff Dep. 184:8-12.

²⁹⁸ *Id.* at 184:13-185:1.

and she has lectured on both. Asbestos has been included in lectures on “air pollutants and cancer-causing agents.”²⁹⁹

J&J inaccurately argues that Dr. Zelikoff is not qualified to offer testimony about asbestos because she has not done “any professional work regarding asbestos.”³⁰⁰ Dr. Zelikoff has worked with asbestos in the context of air pollution.³⁰¹ As an expert in toxicology of environmental chemicals, her expertise extends to asbestos and fibrous talc.³⁰²

VII. CONCLUSION

J&J’s conditional motion should be denied. The PSC’s experts possess the knowledge, skill, experience, training, and education amounting to “specialized expertise” and they meet or exceed the liberal standards of the Third Circuit. They are qualified to testify in this matter concerning all proffered testimony.

Dated: May 29, 2019 Respectfully submitted,

/s/ Michelle A. Parfitt
Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392

²⁹⁹ *Id.* at 165:20-166:4.

³⁰⁰ See Defs.’ Mem., Qualifications, at 35-36.

³⁰¹ Zelikoff Dep. at 178:8 to 178:14.

³⁰² *Id.* at 491:2 to 491:14.

mparfitt@ashcraftlaw.com

/s/ P. Leigh O'Dell

P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com
Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella

Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com
Plaintiffs' Liaison Counsel

PLAINTIFFS' EXECUTIVE COMMITTEE:

Warren T. Burns
BURNS CHAREST LLP
500 North Akard Street, Suite 2810
Dallas, TX 75201
Tel: 469-904-4551
Fax: 469-444-5002
wburns@burnscharest.com

Richard Golomb
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: 215-985-9177
rgolomb@golombhonik.com

Richard H. Meadow
THE LANIER LAW FIRM PC
6810 FM 1960 West
Houston, TX 77069
Tel: 713-659-5200
Fax: 713-659-2204
richard.meadow@lanierlawfirm.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11thFloor
New York, NY 10017
Tel: 212-397-1000
hunter@napolilaw.com

PLAINTIFFS' STEERING COMMITTEE:

Laurence S. Berman
LEVIN, SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: 215-592-1500
Fax: 215-592-4663
lbberman@lfsblaw.com

Timothy G. Blood
BLOOD, HURST & O'REARDON,
LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619-338-1100
Fax: 619-338-1101
tblood@bholaw.com

Sindhu S. Daniel
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, #1100
Dallas, TX 75219
Tel: 214-521-3605
Fax: 214-520-1181
sdaniel@baronbudd.com

Jeff S. Gibson
WAGNER REESE, LLP
11939 N. Meridian St.
Carmel, IN 46032
Tel: (317) 569-0000
Fax: (317) 569-8088
jgibson@wagnerreese.com

Kristie M. Hightower
LUNDY, LUNDY, SOILEAU & SOUTH,
LLP
501 Broad Street
Lake Charles, LA 70601
Tel: 337-439-0707
Fax: 337-439-1029
khightower@lundylawllp.com

Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel: 856-667-0500
Fax: 856-667-5133
dlapinski@motleyrice.com

Victoria Maniatis
SANDERS PHILLIPS GROSSMAN, LLC
100 Garden City Plaza, Suite 500
Garden City, NJ 11530
Tel: 516-640-3913
Fax: 516-741-0128
vmaniatis@thesandersfirm.com

Carmen S. Scott
MOTLEY RICE LLC
28 Bridgeside Boulevard
Mount Pleasant, SC 29464
Tel: 843-216-9162
Fax: 843-216-9450
cscott@motleyrice.com

Eric H. Weinberg
THE WEINBERG LAW FIRM
149 Livingston Avenue
New Brunswick, NJ 08901

Richard L. Root
MORRIS BART, LLC
Pan America Life Center
601 Poydras St., 24th Fl.

Tel: 732-246-7080
Fax: 732-246-1981
ehw@erichweinberg.com

New Orleans, LA 70130
Tel. 504-525-8000
Fax: 504-599-3392
rroot@morrisbart.com

Christopher V. Tisi
LEVIN PAPANTONIO
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7000
ctisi@levinlaw.com